Attorney Docket No.: NET 2-098

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Philip E. Eggers,

Serial No. : 10/630,100

Filed: : July 30, 2003

For: : Electrosurgical Accessing of Tissue with Controlled

Collateral Thermal Phenomena

TC/AU : 3739

Examiner : Michael F. Peffley

Attorney Docket No. : NET 2-098

HONORABLE COMMISSIONER FOR PATENTS MAIL STOP AMENDMENT P.O. BOX 1450 ALEXANDRIA, VA 22313-1450

DECLARATION UNDER 37 CFR 1.132

Philip E. Eggers declares as follows:

- 1) That he is a resident of the State of Ohio, having a residence address at 5366 Reserve Drive, Dublin, Ohio 43017;
- 2) That he holds a Bachelor of Science Degree (Physics), a Master of Science Degree (Physics), and an M.B.A. Degree (Systems Management), all from The Ohio State University;
- 3) That his curriculum vitae is annexed hereto as Exhibit 1;
- 4) That he has been actively involved in research and development in conjunction with the field of medical instrumentation and methodology and is named as an inventor in over 116 U. S. patents and applications for patent;
- 5) That he has been actively involved in the field of electrosurgery since about 1995;
- 6) That he is an inventor named in the above-identified application for United States patent;
- 7) That he has been advised that claims 16-21, 40, 42-48, and 54 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,814,044 issued to Hooven on September 29, 1998 (Hooven);
- 8) That the Examiner has cited Hooven as having an air gap between an outer cannula and an evacuation channel, the air gap inherently acting as a heat transfer isolation mechanism:

- 9) That the Examiner further has cited Hooven at Col. 5, line 40 through Col. 6, line 30 as teaching that the inner and outer tubes may be made from a variety of materials, including thermally insulative plastics or metals coated with insulative plastics;
- 10) That Hooven describes a morselating instrument with an elongated shaft having an inner tube and an outer tube extending between proximal and distal end portions. At least one of the tubes is rotatable and an electrode surface is carried at the distal end of the rotatable tube. In use, the surgeon energizes, rotates and advances the electrode into a tissue volume in order to morselate it. Morselated tissue then is removed by suction through the shaft;
- 11) That Hoover does not identify or address the problem of heat generated from an interstitial electrosurgical cutting procedure, which causes damage to healthy tissue surrounding the instrument;
- 12) That, with the exception of the distal end, the outer tube of Hooven's instrument does not contact patient tissue because Hooven's instrument is used laparoscopically, the surgeon inserting a trocar assembly having a hollow sleeve through the patient's abdominal wall and thereafter inserting Hooven's instrument through the sleeve to access the site where surgeon performs the morselating procedure;
- 13) That the term "insulating" is used in Hooven to mean electrically insulating and not thermally insulating;
- 14) That a heat transfer channel formed of fiberglass epoxy having a thickness of approximately 0.007 inches would be an insufficient thermal barrier to prevent iatrogenic injury;
- 15) That there is no teaching or suggestion that the inner and outer tube materials disclosed in Hooven would be able to withstand the heat produced by the elevated temperature fluids generated during an interstitial electrosurgical cutting procedure;
- That there is no teaching or suggestion that the air gap shown in Hooven, for example in Fig. 6b, would be sufficient for the outer tube to be in heat transfer isolation from the inner tube:
- 17) That it is his considered opinion that Hooven does not anticipate or, in combination with any other cited reference, render obvious the apparatus described and claimed in the above-identified application for United States patent; and
- That all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like, so made, are punishable by fine, or imprisonment, or both, under § 1001 of Title 18,

Attorney Docket No.: NET 2-098

and that such willful false statements may jeopardize the validity of the application or any document resulting therefrom.

Further Declarant sayeth naught.

Date November 3, 2005

Philip E. Egg